

## **REMARKS**

In the Office Action mailed August 9, 2007 from the United States Patent and Trademark Office, the Examiner rejected claims 1-11 under 35 U.S.C. 103(a) as being unpatentable over Kelly (US 6,340,703) in view of Chang et al. (US 2006/00996900 A1) in view of Davis (US 5,708,038) in view of Elkins, R. (1998) in view of Flockhart et al. (WO 9307901 A1).

### **Rejections under 35 U.S.C. § 102(b) and 103(a):**

M.P.E.P. § 2141 sets forth the *Graham* factual enquiries that should be considered when making an obviousness rejection under Section 103: “Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved.” (Citing *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966).) Additionally, one helpful standard for a Section 103 rejection is set forth in M.P.E.P 706.02(j), which provides:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, **the prior art reference (or references when combined) must teach or suggest all the claim limitations.** The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant’s disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

(Emphasis added). Applicant respectfully submits that the references cited by the Examiner, either alone or in combination, do not teach or suggest all the limitations claimed in the claim set provided herein. Applicant also respectfully submits that there is no suggestion or motivation to combine the references in the manner suggested by the Examiner, and that one of skill in the art would not reasonably expect success in combining the references in the manner provided.

Additionally, under Section 103, objective evidence or secondary considerations such as unexpected results, commercial success, long-felt need, failure of others, copying by others, licensing, and skepticism of experts are relevant to the issue of obviousness and must be considered in every case in which they are present. MPEP § 2141.

The pending Action indicates that one of ordinary skill in the art would have been motivated to combine rutin and quercetin as well as a *Morinda citrifolia* leaf extract for inhibiting estrogen production and providing estrogenic effects, and that it would have been obvious to one of ordinary skill in the art to discover the optimum or workable ranges involving only routine skills in the art. However, the claimed invention involves ranges, which produce unexpected results. In particular, at higher concentrations administration of *Morinda citrifolia* leaf extract caused inhibition of enzyme induction as noted on page 23 of the originally filed specification. In this non-limiting example, the *Morinda citrifolia* leaf extract exerted a significant induction of alcoline phosphotase, and maximum effect was achieved at 0.3 ml/ml (representing 30 mg dry leaves/ml); higher concentrations caused an inhibition of enzyme induction. The unexpected result that increased concentrations of *Morinda citrifolia* leaf extracts result in an inhibition of enzyme induction is not taught in the cited references.

Chang discloses only that rutin is a flavanoid glycoside comprised of quercetin and a sugar, rutinose, and that many beneficial health effects of rutin have been demonstrated. Chang fails to disclose the claimed ranges of rutin and quercetin, and fails to teach the unexpected result that higher concentrations cause an inhibition of enzyme induction.

Kelly discloses merely that it is known for example that other compounds present in lignanes such as flavanoids (e.g. quercetin, luteolin, kaempferol and lignans) also are estrogenic. Kelly likewise fails to disclose the claimed ranges of quercetin and rutin, and fails to teach or

fairly suggest the unexpected result that higher concentrations of leaf extract result in inhibition of enzyme induction.

Davis discloses only that estrogens have been isolated from a number of plant sources and that to date, only three sterols having mild estrogenic activity have been isolated. Importantly, Davis teaches that the estrogenic activity of plant sterols has been estimated to be approximately 1/400 of that recorded for estrodile. Accordingly, not only does Davis fail to disclose the claimed ranges of quercetin and rutin, and the unexpected result that higher concentrations cause inhibition of enzyme induction, but Davis additionally teaches away from the use of plant sterols in favor of estrodile, as the plants produce only a mild estrogenic effect, approximately 1/400 of that recorded for estrodile. The magnitude of the unexpected result, as indicated in the table on page 23 of the present invention, is therefore significant and non-obvious in light of the art cited. Accordingly, Applicant respectfully submits the claims provided herein, are not anticipated or rendered obvious by the cited references. Verdegall Bros. v. Union Oil Co. of California, 814 F. 2d 628, 631 (Fed. Cir. 1987).

In addition, a prior art reference that “teaches away” from the claimed invention is a significant factor to be considered in determining obviousness. M.P.E.P. § 2145; *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994) (emphasis added). As indicated above, Davis teaches away from the combination suggested in the pending application by teaching that plant sterols have a mild estrogenic effect approximately 1/400 of that recorded for estrodile. Accordingly, the lack of efficacy of the use of plant sterols in providing an estrogenic effect as taught in Davis, teaches away from the use of plant sterols in an effort to produce an estrogenic effect, and serves to place the unexpected results acquired in the experiments conducted in support of the present invention in light of the lack of efficacy previously achieved.

In fact, it is improper to combine references where the references teach away from their combination. M.P.E.P. § 2145; *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983). “A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant . . . [or] if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant.” *In re Gurley*, 27 F.3d at 553, 31 USPQ2d at 1131 (emphasis added). Because a person of ordinary skill in the art upon reading Davis would be discouraged from utilizing plant sterols in combination as claimed in the present invention, one skilled in the art would not have been motivated to combine the references as cited in the pending application and certainly would not have been motivated to modify the references to read on the claims of the present invention. Accordingly, Applicant respectfully requests that the §103 rejections be withdrawn at this time.

CONCLUSION

Applicant submits that the amendments made herein do not add new matter and that the claims are now in condition for allowance. Accordingly, Applicant requests favorable reconsideration. If the Examiner has any questions or concerns regarding this  
5 communication, the Examiner is invited to call the undersigned.

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Respectfully submitted,

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